

APPENDIX A – ADDITIONAL REFERENCE AND MAILING INFORMATION

1. You may freely photocopy the Form 3500A. Copies are also available by mail and fax.

2. Electronically generated versions of the form 3500A can be submitted to FDA for approval to:

Food and Drug Administration
Center for Devices and Radiological Health
Information and Analysis Branch, HFZ-531
1350 Piccard Drive
Rockville, MD 20850

3. Bulk copies of FDA Form 3500A can be obtained from:

Consolidated Forms and Publications Distribution Center
Beltsville Service Center
6351 Ammendale Road
Beltsville, MD 20705

4. Ten copies or less of the Form 3500A and copies of the MedWatch Reporting Coding Manual can be obtained from:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Small Manufacturers, International & Consumer Assistance, HFZ-220
1350 Piccard Drive
Rockville, MD 20850

Fax number: 301-443-8818

5. The Division of Small Manufacturers Assistance (DSMA) also maintains FACTS-ON-DEMAND (FOD), an automated request line for documents. The FOD phone number is 800-899-0381 or 301-827-0111.

6. The MedWatch Reporting Coding Manual is also available on the internet at www.fda.gov/cdrh/mdrcode.pdf or www.fda.gov/cdrh/ for the Center for Devices and Radiological Health home page.

7. You can fax the completed Form 3500A to CDRH. Call to obtain authorization to fax your report. Reports sent through regular mail should be addressed to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

8. Reports that you send via an overnight carrier should be addressed to:

Food and Drug Administration
Center for Devices and Radiological Health
Information and Analysis Branch, HFZ-531
1350 Piccard Drive
Rockville, MD 20850